510k Submission
Global Treasures Industrial, Inc.
Flexible Tip Thermometer

K030673

510 (K) SUMMARY

Date of Summary

January 26, 2003

APR 0 4 2003

Product Name:

Flexible Tip Thermometer

Manufacturer:
Global Treasures Industrial Ltd.
Nan Fung Ind. Cit
18 Tin Hau Road
Tuen Mun N.T. , HK

Sponsor
Global Treasures, Industrial, Inc.
Nan Fung Ind. Cit
18 Tin Hau Road
Tuen Mun, N.T., HK

Correspondent:
Fran White
MDC Associates
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Device:

Product: GT010706 Digital Thermometer (K021052)
Manufactured by: Global Treasures Industrial, Ltd.

Product Description:

Electronic Thermometer

Intended Use:

The Flexible Tip Thermometer is an electronic thermometer to measure patient body temperature orally, rectally or axilliary (under arm).

The Teddy Bear Flexible Tip Thermometer is intended for professional and over-the-counter use. A pediatric model will be available. The plastic end of the thermometer has a molded Teddy Bea

Performance Characteristics:

The Flexible Tip Thermometer measures patient body temperature in approx. 60 seconds. The thermometer is programmed to display the current body temperature. The temperature detected is graduated on 0.1°F intervals, reading a range of 90.0°F to 109.0°F. The ambient temperature environment in which the device is intended for use is 60.8°-104°F (95% Relative Humidity).

Conclusion:

The Flexible Tip Thermometer substantially equivalent to the electronic thermometer manufactur by Global Treasures. GT010706 Digital Thermometer (K021052).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 4 2003

Global Treasure Industrial Limited
C/O Ms. Fran White
MDC Associates
163 Cabot Street
Beverly, Massachusetts 01915

Re: K030673
Trade/Device Name: Flexible Tip Thermometer
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 25, 2003
Received: March 4, 2003

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510k Submission
Global Treasures Industrial, Inc.
Flexible Tip Thermometer

510(k) Number:

Device Name: **Flexible Tip Thermometer**

Indication for Use:

The Flexible Tip Thermometer is an electronic thermometer to measure patient temperature. Targeted users include professional and over-the-counter users.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over the Counter Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Rebecca Cincotta

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030673